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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,114	04/07/1999	SHIMON SAKAGUCHI	07898/038001	1911
20985	7590	12/24/2003		
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			EXAMINER WILSON, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,114

Applicant(s)

SAKAGUCHI, SHIMON

Examiner

Michael C. Wilson

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11-12-03 has been entered.

The amendment filed 10-14-03 has been entered. Applicant's arguments filed therein have been fully considered but they are not persuasive. Claims 18, 20 and 21 have been canceled. Claim 13 is pending and under consideration in the instant office action. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

The requirements for deposit ATCC accession No. BP-7790 have not been met. The deposit information of SKG embryos provided 2-7-02, paper number 18, does not fulfill the deposit requirements.

1) The deposit information states the SKG embryos were originally deposited 11-6-02, but applicants have not provided a declaration indicating the chain of custody was maintained since the time of filing.

2) The declaration by Dr. Sakaguchi filed 4-22-03 states the mice of deposit BP-7790 are those described on pg 3, lines 6-7, of the specification. However, pg 3, lines 1-7, states

"[a]s a result of his extensive study for solving the problems described above, the present inventor found a mouse with joint swelling among a normal BALB/c colony, and from this finding, attained the present invention. Hence, the present invention is a mouse strain having the character of natural onset of autoimmune arthritis. This mouse strain was designated as the SKG strain."

Pg 3, lines 1-7, does not describe the embryos deposited because it is a discussion generic to at least five types of mice disclosed in the specification in Example 1 (pg 5-6), each of which has a different genotype/phenotype, i.e. BALB/c mice, the founder mouse, 1<sup>st</sup> generation (backcrossed with BALB/c mice), 2<sup>nd</sup> generation (backcrossed with BALB/c mice), and 3<sup>rd</sup> generation mice (backcrossed with BALB/c mice).

Therefore, the declaration does not fulfill the deposit requirement by providing which of the numerous mice disclosed in the specification, having different genotypes and different symptoms of arthritis that were specific to the genotype, were used to make the SKG strain deposited as BP-7790. In addition, pg 3, lines 1-7, does not teach the SKG strain had rheumatoid arthritis or genes that cause natural onset of arthritis as claimed.

As such, the requirements for deposit BP-7790 have not been met.

Applicants argue the backcrosses described in the specification were provided to show allelic variance. Applicants argue the deposited embryos comprise the SKG strain and not the backcrosses based on the SKG strain. Applicants' argument is not persuasive. It cannot be determined that the backcrosses are "based on" the SKG strain rather than the backcrosses being used to make the SKG strain. It cannot be

determined from applicants arguments which of the 5 strains described on pg 3, lines 1-7, is the SKG strain or was deposited as BP-7790 as claimed. Nor is it readily apparent which mouse described in the specification is the SKG strain.

### ***Summary of the invention***

Applicants disclose a founder female derived from BALB/C mice having joint swelling (pg 4, Example 1), a first generation obtained from breeding the founder female with a BALB/C mouse, 4/12 of which have joint swelling (pg 5, line 1), a second generation obtained from breeding a first generation mouse (having joint swelling) with a BALB/c mouse, wherein 6/15 of the second generation had joint swelling, and a third generation obtained from breeding a second generation mouse (having joint swelling) with a BALB/c mouse, wherein 10/28 of the third generation had joint swelling (pg 5, 1<sup>st</sup> para.).

It was determined "in later experiments, the BALB/c mice considered normal and apparently free of swelling in large joints (e.g. leg joints), were found by detailed observation for a long period (6 months or more) to have joint swelling in small joints of the fingers" (pg 5, lines 22-26). The specification states the incidence of arthritis was 100% taking into account large or small joint arthritis (§ bridging pg 5-6); it assumed this statement refers to BALB/c mice. The specification states "[b]y later experiments on the inheritance in a large scale, it was reasonably estimated that the genetic abnormality causing the natural onset of autoimmune arthritis is autosomal and recessive. The SKG mice are therefore maintained at present as homozygotes. Their incidence of arthritis is almost 100%, and the penetrance of the genetic abnormality in the homozygous is considered to be almost 100% in the environment where they are currently maintained" (pg 6, lines 3-8). Overall, the specification does not describe which generation of mice are the SKG strain, which mice were used to make the embryos deposited as BP-7790, or the genotype/phenotype of the SKG strain or the mouse strain deposited as BP-7790.

***Claim Rejections - 35 USC § 101***

I. Claim 13 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 13 require a "mouse or mouse strain that exhibits a phenotype comprising immunopathological characteristics indicative of autoimmune arthritis obtained from an embryo deposited as accession no. FERM BP-7790". The mouse in claim 13 is a

naturally occurring product. Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg 717-722) taught breeding BALB/c mice and screening the offspring, wherein the offspring had symptoms of rheumatoid arthritis in joints of the foot. Thus, the mice derived naturally from the BALB/c strain had symptoms of rheumatoid arthritis in joints of the foot (pg Table 1, see BALB/c, male). Therefore, the claim is equivalent to naturally occurring BALB/c mice and is non-statutory subject matter.

***New Matter***

II. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13 requires a mouse or mouse strain that has characteristics of autoimmune arthritis obtained from an embryo of the deposit BP-7790. Applicants point to pg 2, lines 20-21, and pg 3, lines 1-7. However, the citations do not teach the mouse of the invention, particularly the SKG line described on pg 3, line 7, is equivalent the embryos of BP-7790. Nowhere does the specification teach that mice made from embryos of BP-7790 have rheumatoid arthritis as described on pg 2, lines 20-21.

***Written description***

III. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 13 requires the limitation of "ATCC accession No. BP-7790". The deposit information of SKG embryos provided 2-7-02, paper number 18, does not fulfill the deposit requirements for reasons cited above. The genotype of the SKG strain cannot be determined from pg 3, lines 1-7, or how it was obtained. As such, the specification does not adequately describe the genotype or phenotype of the SKG strain or of the embryos deposited as BP-7790.

Claim 13 lacks written description. Nowhere does the specification describe the genotype or phenotype of mice from an embryo deposited as BP-7790. It cannot be determined if a mouse from an embryo of BP-7790 is equivalent to the BALB/c mice, the founder mouse, the 1<sup>st</sup>, 2<sup>nd</sup>, or 3<sup>rd</sup> generation mice described in the specification which all have natural onset of rheumatoid arthritis. Without evidence to the contrary, the BALB/c mice, the founder mouse, the 1<sup>st</sup>, 2<sup>nd</sup>, or 3<sup>rd</sup> generation mice all are homozygous for a gene that causes natural onset of arthritis because they all have natural onset of arthritis. It cannot be determined which mice in the specification have the same genotype as an embryo of BP-77909. Therefore, the claim lacks written description.

Applicants argue the amendment to the claim obviates the rejection. Applicants' argument is not persuasive for the reasons in the paragraph above.

***Indefiniteness***

IV. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite. Nowhere does the specification describe the genotype or phenotype of mice from an embryo deposited as BP-7790. It cannot be determined if a mouse from an embryo of BP-7790 is equivalent to the BALB/c mice, the founder mouse, the 1<sup>st</sup>, 2<sup>nd</sup>, or 3<sup>rd</sup> generation mice described in the specification which all have natural onset of rheumatoid arthritis. Without evidence to the contrary, the BALB/c mice, the founder mouse, the 1<sup>st</sup>, 2<sup>nd</sup>, or 3<sup>rd</sup> generation mice all are homozygous for a gene that causes natural onset of arthritis because they all have natural onset of arthritis. Mice having the same structure of a mouse from an embryo of BP-77909 cannot be determined. Therefore, the metes and bounds of mice encompassed by the claim cannot be determined.

Applicants argue the amendment to the claim obviates the rejection. Applicants' argument is not persuasive for the reasons in the paragraph above.

***Claim Rejections - 35 USC § 102***

V. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Nordling of record (1992, Arthritis and Rheumatism, Vol. 35, pg 717-722).

Nordling taught mice derived from the BALB/c strain having symptoms of rheumatoid arthritis in joints of the foot (pg Table 1, see BALB/c, male). The mice exhibit the same characteristics of autoimmune arthritis as mice described in the specification and, therefore, have the same structure as mice obtained from an embryo deposited as BP-7790 as claimed.

VI. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Yamanaka et al. (US Patent 4,950,741).

Yamanaka taught a breeding BALB/c mice and obtaining a BALB/c mouse that developed antibodies against a rheumatoid arthritis-specific protein, which is a trait of rheumatoid arthritis. The mice exhibit the same characteristics of autoimmune arthritis as mice described in the specification and, therefore, have the same structure as mice obtained from an embryo deposited as BP-7790 as claimed.

Applicants argue Yamanaka did not teach obtaining a mouse having a characteristic of rheumatoid arthritis. Applicants' argument is not persuasive because the mice had antibodies against an arthritis-specific protein.

***Conclusion***

No claim is allowed.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120. The Examiner's number will be changed on January 12<sup>th</sup>, 2004 to 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



**MICHAEL WILSON**  
**PRIMARY EXAMINER**